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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/603,317	06/25/2003	Howard Scalzo	ETH1690CIP	3087

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EXAMINER
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MENDOZA, MICHAEL G

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 09/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	<b>Application No.</b> 10/603,317	<b>Applicant(s)</b> SCALZO ET AL.	
	<b>Examiner</b> Michael G. Mendoza	<b>Art Unit</b> 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 25 June 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 9-16 is/are allowed.
- 6) ☒ Claim(s) 1-8 and 17-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some    \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>7/28/03, 1/26/04, 7/6/04</u> | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-8 and 19 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hermes et al. 5037429.

3. Claims 1-8 are product-by-process claims. The claimed product appears to be the same or similar to that of the prior art, although produced by a different process. A product-by-process claim is not limited to the manipulation of the recited steps, only the structure implied by the steps.

4. Hermes et al. teaches an antimicrobial suture and an antimicrobial agent with a package; the antimicrobial agent being selected from the group consisting of halogenated hydroxyl ethers, acyloxydiphenyl ethers, and combinations thereof (see abstract and col. 4, lines 49-54); wherein the antimicrobial agent source is an antimicrobial agent-loaded reservoir; wherein the antimicrobial agent source is position within the package; wherein the antimicrobial agent source is on the inner surface of the package; wherein the antimicrobial agent source is integral with one or more packaging components in the package or the package; and wherein the medical device comprises one or more surfaces having an antimicrobial agent disposed thereon (col. 3, lines 23-28).

Art Unit: 3731

5. Claims 1-8 and 19 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kaplan et al. 5222978.

6. Kaplan et al. teaches an antimicrobial suture and an antimicrobial agent with a package; the antimicrobial agent being selected from the group consisting of halogenated hydroxyl ethers, acyloxydiphenyl ethers, and combinations thereof (col. 14, lines 33-51); wherein the antimicrobial agent source is an antimicrobial agent-loaded reservoir; wherein the antimicrobial agent source is position within the package; wherein the antimicrobial agent source is on the inner surface of the package; wherein the antimicrobial agent source is integral with one or more packaging components in the package or the package; and wherein the medical device comprises one or more surfaces having an antimicrobial agent disposed thereon (see abstract).

7. Claims 17 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Fan EP 0 761 243 A1.

8. Fan teaches a method for making an antimicrobial medical device comprising the steps of: exposing a medical device to an antimicrobial agent source; and subjecting the medical device and the antimicrobial agent source to time, temperature and pressure conditions sufficient to vapor transfer an effective amount of the antimicrobial agent from the antimicrobial agent source to the medical device, thereby substantially inhibiting bacterial colonization on the medical device; wherein the time, temperature and pressure conditions to vapor an effective amount of the antimicrobial agent from the antimicrobial agent source to the medical device are a pressure and a temperature sufficient to render a partial pressure for the antimicrobial agent that is the same as or

Art Unit: 3731

greater than the partial pressure rendered under a temperature of 40<sup>0</sup>C and atmospheric pressure, and a period of time ranging from 4 to 8 hours (page 4, line 53 – page 5, line1).

***Allowable Subject Matter***

9. Claims 9-16 are allowable over the prior art of record.
10. The following is a statement of reasons for the indication of allowable subject matter: the prior art of record fails to teach or render obvious the overall method for making an antimicrobial suture comprising the steps of: subjecting a package, a suture and a antimicrobial agent source to time, temperature and pressure conditions sufficient to vapor transfer an effective amount of the antimicrobial agent from the antimicrobial source to the suture, thereby substantially inhibiting bacterial colonization on the suture.

***Contacts***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Mendoza whose telephone number is (571) 272-4698. The examiner can normally be reached on Mon.-Fri. 8:00 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on (571) 272-44963. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Art Unit: 3731

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



MM



GLENN K. DAWSON  
PRIMARY EXAMINER